



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 890

[Docket No. FDA-2012-N-0378]

Physical Medicine Devices; Reclassification and Renaming of Shortwave Diathermy for All Other Uses

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed order; technical correction.

SUMMARY: The Food and Drug Administration (FDA) is proposing to reclassify the shortwave diathermy (SWD) for all other uses, a preamendments class III device, into class II (special controls), and to rename the device "nonthermal shortwave therapy (SWT)." FDA is proposing this reclassification on its own initiative based on new information. FDA is also proposing a technical correction in the regulation for the carrier frequency for SWD and nonthermal SWT devices. This proposed action would implement certain regulatory requirements.

DATES: Submit either electronic or written comments on this proposed order by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. FDA intends that SWD devices for all other uses must comply with the special controls and must submit a premarket notification (510(k)) within 60 days after the effective date of the final order. See Section XII for the proposed effective date of a final order based on this proposed order.

ADDRESSES: You may submit comments, identified by Docket No. FDA-2012-N-0378, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following way:

- Mail/Hand delivery/Courier (for paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA-2012-N-0378 for this rulemaking. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Melissa Burns, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1646, Silver Spring, MD 20993, 301-796-5616, Melissa.Burns@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background--Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Pub. L. 94-295), the Safe Medical Devices Act of 1990 (Pub. L. 101-629), the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105-115), the Medical Device User Fee and Modernization Act of 2002 (Pub. L. 107-250), the Medical Devices Technical Corrections Act of 2004 (Pub. L. 108-214), the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110-85), and the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112-144) established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three categories (classes) of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Section 513(a)(1) of the FD&C Act defines class II devices as those devices for which the general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but for which there is sufficient information to establish special controls to provide such assurance.

Under section 513 of the FD&C Act, devices that were in commercial distribution before the enactment of the 1976 amendments, May 28, 1976 (generally referred to as preamendments devices), are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final

regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976 (generally referred to as postamendments devices), are automatically classified by section 513(f) of the FD&C Act into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval unless, and until, the device is reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

On July 9, 2012, FDASIA was enacted. Section 608(a) of FDASIA amended section 513(e) of the FD&C Act, changing the process for reclassifying a device from rulemaking to an administrative order. Section 513(e) of the FD&C Act governs reclassification of classified preamendments devices. This section provides that FDA may, by administrative order, reclassify a device based upon "new information." FDA can initiate a reclassification under section 513(e) of the FD&C Act or an interested person may petition FDA to reclassify a preamendments device. The term "new information," as used in section 513(e) of the FD&C Act, includes information developed as a result of a reevaluation of the data before the Agency when the device was originally classified, as well as information not presented, not available, or not developed at that time. (See, e.g., Holland Rantos v. United States Department of Health, Education, and Welfare, 587 F.2d 1173, 1174 n.1 (D.C. Cir. 1978); Upjohn v. Finch, 422 F.2d 944 (6th Cir. 1970); Bell v. Goddard, 366 F.2d 177 (7th Cir. 1966).)

Reevaluation of the data previously before the Agency is an appropriate basis for subsequent regulatory action where the reevaluation is made in light of newly available regulatory authority (see Bell v. Goddard, supra, 366 F.2d at 181; Ethicon, Inc. v. FDA, 762 F.Supp. 382, 389-391 (D.D.C. 1991)) or in light of changes in "medical science" (see Upjohn v. Finch, supra, 422 F.2d at 951). Whether data before the Agency are past or new data, the "new information" to support reclassification under section 513(e) must be "valid scientific evidence," as defined in 21 CFR 860.7(c)(2). (See, e.g., General Medical Co. v. FDA, 770 F.2d 214 (D.C. Cir. 1985); Contact Lens Mfrs. Assoc. v. FDA, 766 F.2d 592 (D.C. Cir.), cert. denied, 474 U.S. 1062 (1986)).

FDA relies upon "valid scientific evidence" in the classification process to determine the level of regulation for devices. To be considered in the reclassification process, the valid scientific evidence upon which the Agency relies must be publicly available. Publicly available information excludes trade secret and/or confidential commercial information, e.g., the contents of a pending PMA. (See section 520(c) of the FD&C Act (21 U.S.C. 360j(c)).) Section 513(e)(1) of the FD&C Act sets forth the process for issuing a final reclassification order. Specifically, prior to the issuance of a final order reclassifying a device, the following must occur: (1) Publication of a proposed reclassification order in the Federal Register; (2) a meeting of a device classification panel described in section 513(b) of the FD&C Act; and (3) consideration of comments to a public docket.

In accordance with section 513(e)(1) of the FD&C Act, the Agency is proposing, based on new information that has come to the Agency's attention, to reclassify SWD for all other uses because general controls and special controls are sufficient to provide a reasonable assurance of safety and effectiveness. Therefore, this order proposes to reclassify SWD for all other uses into

class II (special controls) and to rename the device nonthermal SWT; see Section III for more information on the name change. In addition, in this proposed order to reclassify the device to class II with special controls, FDA requires manufacturers of currently marketed SWD for all other uses to submit 510(k)s.

Section 510(m) of the FD&C Act provides that a class II device may be exempted from the premarket notification requirements under section 510(k) of the FD&C Act, if the Agency determines that premarket notification is not necessary to assure the safety and effectiveness of the device. FDA has determined that premarket notification is necessary to assure the safety and effectiveness of SWD for all other uses.

II. Regulatory History of the Device

On November 23, 1983, in the Federal Register (48 FR 53047), FDA published a final rule for classification of SWD for all other uses as class III requiring premarket approval based on recommendations made by the Physical Medicine Device Classification Panel of 1979 (the 1979 Panel). The 1979 Panel made preliminary classification recommendations for physical medicine devices during a series of meetings: August 14 and 15, 1975, March 21 and 22, 1976, March 18, 1977, October 14, 1977, and March 17, 1978. Included in this group of devices were SWD devices. The 1979 Panel recommended splitting the classification for SWD devices: SWD devices that are capable of generating therapeutic heat in specific areas of the body were recommended to be class II. However, SWD devices for any use other than delivering therapeutic deep heat (also referred to as nonthermal SWD) were recommended to be class III.

In 1987, FDA published a clarification by inserting language in the codified language stating that no effective date had been established for the requirement for premarket approval for

SWD devices for any use other than delivering therapeutic deep heat (52 FR 17732, May 11, 1987).

In 2009, FDA published an order in the Federal Register under section 515(i) of the FD&C Act (21 U.S.C. 360i) to call for information on the remaining class III 510(k) devices (74 FR 16214, April 9, 2009). In response to that order, FDA received submissions from five SWD device manufacturers suggesting that nonthermal SWD devices could be reclassified to class II. The manufacturers stated that safety and effectiveness of these devices may be assured by general and special controls. Prior to enactment of FDASIA, FDA published a proposed rule in the Federal Register (77 FR 39953, July 6, 2012) to require filing of PMAs for nonthermal SWD devices. FDA received over 240 comments to the docket in response to the 2012 proposed rule. Comments that expressed an opinion about the classification of nonthermal SWD devices were usually in favor of a class II designation. Some comments did not openly state an opinion, but included arguments against the proposed rule that could reasonably be interpreted as support for a class II designation. There were also comments that agreed with a class III designation. In addition to the comments, FDA received five separate submissions to request a change in the classification of nonthermal SWD from class III to class II.

Subsequent to the issuance of the proposed rule, FDASIA made amendments to section 513 of the FD&C Act that required FDA to hold a panel meeting on the classification of preamendment devices and publish an administrative order for reclassification of preamendment devices instead of rulemaking. On May 21, 2013, FDA held a meeting of the Orthopedic and Rehabilitation Devices Panel (the 2013 Panel), to discuss the classification of nonthermal SWD devices. There was panel consensus that although the effectiveness data were very limited, nonthermal SWD devices did not necessarily fit the regulatory definition of a class III device

(life supporting, life sustaining, or of substantial importance to health). Coupled with the rationale that special controls could be established to reasonably demonstrate an assurance of safety and effectiveness, the 2013 Panel recommended the device be class II (special controls) for nonthermal SWD devices (Ref. 1). FDA is issuing this proposed order to comply with the procedural requirements created by FDASIA. As a result, elsewhere in this issue of the Federal Register, FDA is withdrawing the proposed rule issued on July 6, 2012, calling for PMAs and PDPs for this device pursuant to 515(b) of the FD&C Act. However, FDA continues to review the merits of the submissions for requests for reclassification that meet the requirements under 21 CFR 860.123, submitted in response to the proposed rule.

III. Device Description

SWD devices intended for therapeutic use produce a radiofrequency (RF) signal that is generated by electronic circuitry at one of two frequencies designated by the U.S. Federal Communications Commission (FCC): 27.12 or 13.56 megahertz (MHz) to induce electrical currents and voltages in body tissues. The RF signal is delivered to an antenna or applicator that produces electromagnetic fields external to the applicator. Electric and magnetic fields are induced in body tissues by the applicator.

FDA has differentiated two types of SWD devices that have been cleared through the 510(k) process: thermal and nonthermal. Thermal SWD devices are designed to deliver therapeutic deep heat below the surface of the skin. Nonthermal SWD devices do not provide therapeutic deep heat and do not intend to demonstrate a sustained temperature increase within the tissue. Nonthermal SWD devices are intended to produce their effect in tissue only through means other than therapeutic deep heating.

Because the term diathermy refers to therapeutic elevation of temperature in the tissues, nonthermal diathermy is a misnomer. FDA is proposing in this order to modify the name of the identification from how it is presently written in § 890.5290(b) (21 CFR 890.5290(b)) for additional clarification. FDA is proposing to rename this class of devices from SWD for all other uses to SWT.

Equipment to deliver SWT can be designed to emit either a pulsatile (pulsed) or a continuous wave output and sometimes provides both types of output. Thermal SWD systems cleared by FDA provide continuous wave or pulsed output and achieve therapeutic deep heating of tissues as noted above. Nonthermal SWT devices cleared by FDA deliver RF energy only in a pulsatile fashion and do not provide therapeutic deep heat to the tissues.

IV. Proposed Reclassification

FDA is proposing that SWD for all other uses be reclassified from class III to class II. FDA is also proposing to rename these devices from "shortwave diathermy for all other uses" to "nonthermal shortwave therapy." In this proposed order, the Agency has identified special controls under section 513(a)(1)(B) of the FD&C Act that, if finalized, together with general controls (including prescription-use restrictions) applicable to the devices, would provide reasonable assurance of their safety and effectiveness. Absent the special controls identified in this proposed order, general controls applicable to the device are insufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, in accordance with sections 513(e) and 515(i) of the FD&C Act and § 860.130 (21 CFR 860.130), based on new information with respect to the devices and taking into account the public health benefit of the use of the device and the nature and known incidence of the risks of the device, FDA, on its own initiative, is proposing to reclassify this preamendments class III

device into class II. FDA believes that this new information is sufficient to demonstrate that the proposed special controls can effectively mitigate the risks to health identified in Section V, and that these special controls, together with general controls, will provide a reasonable assurance of safety and effectiveness for nonthermal SWT devices.

Section 510(m) of the FD&C Act authorizes the Agency to exempt class II devices from premarket notification (510(k)) submission. FDA has considered nonthermal SWT devices in accordance with the reserved criteria set forth in section 513(a) of the FD&C Act and has determined that the device does require premarket notification (510(k)). Therefore, the Agency does not intend to exempt this proposed class II device from premarket notification (510(k)) submission as provided for under section 510(m) of the FD&C Act. As stated in Section I, FDA will also require manufacturers of currently marketed SWD for all other uses devices to submit 510(k)s.

FDA is also proposing a technical correction in the regulation for the carrier frequency for these devices from "13 MHz to 27.12 MHz" to "13.56 MHz or 27.12 MHz." The FCC has allocated the shortwave frequencies of 13.56 MHz and 27.12 MHz for medical equipment (Ref. 2). This applies to both SWD devices for use in applying therapeutic deep heat for selected medical conditions (§ 890.5290(a)) and nonthermal SWT devices (§ 890.5290(b)).

V. Risks to Health

After considering available information, including the recommendations of the panel meeting on nonthermal SWT devices held on May 21, 2013, FDA has reevaluated the risks to health associated with the use of nonthermal SWT and made revisions from those previously identified in a proposed rule issued in the Federal Register on July 6, 2012 (77 FR 39953). FDA has determined that the following risks to health are associated with the use of nonthermal SWT:

- Cellular or tissue injury: Nonthermal biological effects of nonionizing radiation may cause cellular or tissue injury.
- Electromagnetic interference: The electromagnetic fields generated by the device may interfere with the circuitry of other patient systems, causing adverse events in the patient, as well as adversely affecting the performance of the other patient systems, such as cardiac pacemaker and implantable defibrillator.
- Tissue necrosis (tissue death) and burns: Excessive energy deposition into the tissue may cause excessive heating that results in tissue damage.
- Electrical shock: Electrical shock hazards may pose a potential hazard to both operators and users. Excessive leakage current from the device could result in injury, or a malfunction of the device could result in electrical shock.
- Thermal injury from implanted leads and implanted systems with leads: Interaction of the RF energy with an implanted lead may cause excessive heating in the tissue surrounding the lead electrodes.
- Adverse tissue reaction: Device materials that are not biocompatible may either directly or through the release of their material constituents: (i) produce adverse local or systemic effects, (ii) be carcinogenic, or (iii) produce adverse reproductive and developmental effects. Although medical devices may have myriad biocompatibility issues, the biocompatibility concerns from nonthermal SWT devices are likely limited to skin reactions from contact with the materials from which the applicator is made.
- Adverse pregnancy outcome: Exposure to the device during pregnancy can lead to congenital anomalies.

- Risk to children: Exposure to the device can affect the growth plates in children if applied over the growth plates.
- Ineffective treatment: Ineffective treatments can result in increased morbidity, delayed discharge after ambulatory surgery, and hospital readmission.

The following additional risks to health were identified by the submitters and acknowledged by the 2013 Panel: Pain, bleeding, feeling chilly and cold in response to treatment, pins and needles sensation, gout attack in patients with pre-existing gout, mild numbness in the area of treatment, abdominal pain, chest wall sensation, malaise, and headache. Many of these are infrequent and related to pain (which is already present in this patient population), the underlying condition being treated, or to the surgical procedures that precede the use of the device. Therefore, FDA does not consider these additional risks to health as being associated with the use of nonthermal SWT. The 2013 Panel also acknowledged the risk of cancer progression and metastasis, although there was some disagreement among panel members on whether it should be included. This risk was primarily based on literature from in vitro test data, which associates device use with the upregulation of certain cytokines and proteases that play a role in metastasis. FDA is not aware of any animal data, clinical data, or adverse event reports that attribute cancer progression or metastasis to nonthermal SWT. Therefore, FDA does not consider this a risk as being associated with the use of nonthermal SWT.

VI. Summary of Reasons for Reclassification

Based on the comments from the 2013 Panel meeting, the comments received in response to FDA's prior proposed rule (77 FR 39953, July 6, 2012), and FDA's assessment of new, valid scientific data related to the health benefits and risks associated with nonthermal SWT, FDA is proposing that these devices should be reclassified from class III to class II because special

controls, in addition to general controls, can be established to provide reasonable assurance of safety and effectiveness of the device, and because general controls themselves are insufficient to provide a reasonable assurance of its safety and effectiveness. In addition, there is now sufficient information to establish special controls to provide such assurance.

FDA has been reviewing these devices for many years, and their risks are well known. A review of the applicable clinical literature indicates that few relevant adverse events have been reported for these devices or related devices suggesting that the device has a long-term safety profile. If properly manufactured and used as intended, FDA believes that the special controls identified in this proposed order, if finalized, together with general controls (including prescription-use restrictions and 510(k) notification requirements), are adequate to provide a reasonable assurance of safety and effectiveness for this device.

VII. Summary of Data Upon Which the Reclassification is Based

FDA believes that the identified special controls, in addition to general controls, are sufficient to provide reasonable assurance of safety and effectiveness of these devices. Therefore, in accordance with sections 513(e) and 515(i) of the FD&C Act and § 860.130, based on new information with respect to the device and taking into account the public health benefit of the use of the device and the nature and known incidence of the risk of the device, FDA, on its own initiative, is proposing to reclassify this preamendments class III device into class II. The Agency has identified special controls that would provide reasonable assurance of their safety and effectiveness. FDA's review of the clinical literature has been previously summarized in the Executive Summary to the 2013 Panel meeting to discuss nonthermal SWT classification (Ref. 3).

In addition, the 2013 Panel reviewed and discussed recent information presented by FDA, manufacturers of SWT devices, and members of the public. This information included recent literature regarding the possible risks to health and a review of FDA's Manufacturer and User Facility Device Experience database.

The 2013 Panel agreed that nonthermal SWT devices are not "life-supporting or life-sustaining, or of substantial importance in preventing impairment of human health." The 2013 Panel agreed on the potential risks to health identified by FDA and the additional risks to health identified in the comments received in response to the July 6, 2012, proposed rule (77 FR 39953). However, the 2013 Panel expressed uncertainty regarding "abnormal cell growth" as a risk to health, but suggested that cell membrane injury is also a potential risk to health. The 2013 Panel recommended that the following additional risks to health be included, as they were reported by those who submitted requests to change the classification: Adverse pregnancy outcome, cancer and tumor promotion, skin reactions, pain, bleeding, ineffective treatment, risk to children, feeling chilly and cold in response to treatment, sensation of localized warmth, pins and needles sensation, gout attack in patients with pre-existing gout, mild numbness in the area of treatment, abdominal pain, chest wall sensation, and headache. FDA acknowledges cellular or tissue injury, electromagnetic interference, tissue necrosis (tissue death) and burns, electrical shock, thermal injury from implanted leads and implanted systems with leads, adverse tissue reaction, adverse pregnancy outcome, risk to children, and ineffective treatment as risks to health for these devices. As explained in Section V, FDA does not believe valid scientific evidence supports the other additional risks identified by the 2013 Panel as being associated with the use of nonthermal SWT.

Regarding the benefits of nonthermal SWT devices, the 2013 Panel indicated that a certain subset of patients may benefit, but there were concerns about the veracity and the limitations of clinical trials reported in the literature. They further commented that there was limited clinical evidence presented to demonstrate effectiveness. The most compelling effectiveness evidence was presented for post-breast surgery. The 2013 Panel noted that the effect on edema was less convincing.

Regarding classification, there was general panel consensus that nonthermal SWT devices for adjunctive used in palliative treatment of postoperative pain and edema should be class II devices with special controls. There was also general consensus by the 2013 Panel that special controls that included labeling, biocompatibility testing, electrical safety testing, electromagnetic compatibility, nonclinical performance testing, and clinical performance data were appropriate. The 2013 Panel recommended that clinical data are necessary as a special control and also recommended studies should include the following basic study design elements:

- Randomization;
- Sham control group;
- Well-defined patient population, e.g. patients having a specific surgical procedure;
- Well-defined SWT treatment parameters and device settings;
- Clinically relevant validated measures of effectiveness;
- Adequate power and sample size;
- Appropriate predefined statistical methods;
- Predefined hypothesis and success criteria; and
- Systematic collection of adverse events.

No 2013 Panel member recommended leaving these devices in class III. Regarding the issue of general controls, the 2013 Panel agreed that general controls alone are not sufficient to provide reasonable assurance of the safety and effectiveness of nonthermal SWT devices.

VIII. Proposed Special Controls

FDA believes that the following special controls, in addition to general controls, are sufficient to mitigate the risks to health described in Section V:

1. Components of the device that come into human contact must be demonstrated to be biocompatible. These devices can contact users' skin directly; therefore, a demonstration of biocompatibility would mitigate the risks of skin reactions.
2. Appropriate analysis/testing must demonstrate that the device is electrically safe and electromagnetically compatible in its intended use environment. The requirement to demonstrate electromagnetic compatibility would, in concert with other special controls, help ensure the mitigation of discomfort, pain, and tenderness resulting from burns to the skin due to excessive energy deposition by preventing electromagnetic interference with device hardware and software. In addition, this requirement would ensure the device does not interfere with other electrical equipment and would also ensure that both operators and users are properly protected from electrical hazards such as electrical shock.
3. Non-clinical testing must demonstrate that the device performs as intended under anticipated conditions of use. Non-clinical performance testing must characterize the output waveform of the device and demonstrate that the device meets appropriate output performance specifications. This requirement would mitigate the risks of cellular or tissue injury, electromagnetic interference, tissue necrosis and burn, and

thermal injury from implanted leads and implanted systems. The output characteristics and the methods used to determine these characteristics, including the following, must be determined:

- Peak output power;
 - Pulse width;
 - Pulse frequency;
 - Duty cycle;
 - Characteristics of other types of modulation that may be used;
 - Average measured output powered into the RF antenna/applicator;
 - Specific absorption rates in saline gel test load;
 - Characterization of the electrical and magnetic fields in saline gel test load for each RF antenna and prescribed RF antenna orientation/position ; and
 - Characterization of the deposited energy density in saline gel test load.
4. Documented clinical performance testing must demonstrate safe and effective use of the device. This requirement would mitigate ineffective treatment.
 5. The labeling must include a detailed summary of the clinical testing pertinent to the use of the device and a summary of the adverse events and complications. This requirement would help mitigate the risk of adverse pregnancy outcome, risk to children, thermal injury from implanted leads and implanted systems with leads, electromagnetic interference, electric shock, tissue necrosis and burn, adverse tissue reaction, and ineffective treatment.

Table 1 shows how FDA believes that the risks to health identified in Section V can be mitigated by the proposed special controls.

Table 1.--Health Risks and Mitigation Measures for Nonthermal SWT

Identified Risk	Mitigation Measure
Cellular or tissue injury	Non-clinical characterization and performance testing
Electromagnetic interference	Electromagnetic compatibility testing Non-clinical characterization and performance testing Labeling
Tissue necrosis (tissue death) and burns	Non-clinical characterization and performance testing Electrical Safety Testing Labeling
Electrical shock	Electrical safety testing Labeling
Thermal injury from implanted leads and implanted systems with leads	Non-clinical characterization and performance testing Labeling
Adverse tissue reaction	Biocompatibility Labeling
Adverse pregnancy outcome	Labeling
Risk to children	Labeling
Ineffective treatment	Clinical performance data Labeling

In addition, under 21 CFR 801.109, the sale, distribution, and use of these devices are restricted to prescription use. Prescription use restrictions are a type of general controls in section 513(a)(1)(A)(i) of the FD&C Act. Also, under 21 CFR 807.81, the device would continue to be subject to 510(k) notification requirements.

IX. Environmental Impact

The Agency has determined under 21 CFR 25.34(b)) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

X. Paperwork Reduction Act of 1995

This proposed order refers to currently approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in part 807, subpart E, have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 814, subpart B, have been

approved under OMB control number 0910-0231; and the collections of information under 21 CFR part 801 have been approved under OMB control number 0910-0485.

No burden shift is associated with the reclassification of the device. This is currently a class III device for which manufacturers must submit a premarket notification (510(k)). This order proposes to reclassify the device into class II, therefore, respondents would continue to submit a premarket notification.

XI. Codification of Orders

Prior to the amendments by FDASIA, section 513(e) of the FD&C Act provided for FDA to issue regulations to reclassify devices. Although section 513(e) of the FD&C Act as amended requires FDA to issue final orders rather than regulations, FDASIA also provides for FDA to revoke previously issued regulations by order. FDA will continue to codify classifications and reclassifications in the Code of Federal Regulations (CFR). Changes resulting from final orders will appear in the CFR as changes to codified classification determinations or as newly codified orders. Therefore, under section 513(e)(1)(A)(i), as amended by FDASIA, in this proposed order we are proposing to revoke the requirements in § 890.5290(b)(1) related to the classification of shortwave diathermy devices for all other uses as class III devices and to codify the reclassification of nonthermal SWT devices into class II (special controls).

XII. Proposed Effective Date

FDA is proposing that any final order based on this proposed order become effective on the date of its publication in the Federal Register or at a later date if stated in the final order. FDA proposes that nonthermal SWT devices must comply with the special controls and must submit a 510(k) within 60 days after the effective date of the final order. FDA requests comment

on whether 60 days is an appropriate time to allow manufacturers to prepare and submit 510(k)'s for these devices.

XIII. Comments

Comments submitted to the previous docket (Docket No. FDA-2012-N-0378) have been officially noted and do not need to be resubmitted. FDA has considered previous docket comments before issuing this proposed order. Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see ADDRESSES) or electronic comments to <http://www.regulations.gov>. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

XIV. References

The following references have been placed on display in the Division of Dockets Management (see ADDRESSES), and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at <http://www.regulations.gov>. (FDA has verified the Web site addresses, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.)

1. FDA's Orthopedic and Rehabilitation Devices Panel transcript and other meeting materials are available on FDA's Web site at <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/OrthopaedicandRehabilitationDevicesPanel/ucm352525.htm>.

2. 47 CFR Part 18--Industrial, Scientific, And Medical Equipment, Subpart C, § 18.301 is available at <http://www.gpo.gov/fdsys/pkg/CFR-2009-title47-vol1/xml/CFR-2009-title47-vol1-part18.xml>.
3. Executive Summary of the Orthopedic and Rehabilitation Devices Panel meeting is available at <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/OrthopaedicandRehabilitationDevicesPanel/ucm352525.htm>.

List of Subjects in 21 CFR Part 890

Medical devices, Physical medicine devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq., as amended) and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 890 be amended as follows:

PART 890--PHYSICAL MEDICINE DEVICES

1. The authority citation for 21 CFR part 890 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 890.5290 is amended by revising paragraphs (a)(1) and (b), and removing paragraph (c) to read as follows:

§ 890.5290 Shortwave diathermy.

(a) Shortwave diathermy for use in applying therapeutic deep heat for selected medical conditions--(1) Identification. A shortwave diathermy for use in applying therapeutic deep heat for selected medical conditions is a device that applies to specific areas of the body electromagnetic energy in the radiofrequency (RF) bands of 13.56 megahertz or 27.12 megahertz

and that is intended to generate deep heat within body tissues for the treatment of selected medical conditions such as relief of pain, muscle spasms, and joint contractures, but not for the treatment of malignancies.

(2) * * *

(b) Nonthermal shortwave therapy--(1) Identification. A nonthermal shortwave therapy is a prescription device that applies to the body pulsed electromagnetic energy in the RF bands of 13.56 megahertz or 27.12 megahertz and that is intended for the treatment of medical conditions except for the treatment of malignancies by means other than the generation of deep heat within body tissues as described in paragraph (a) of this section.

(2) Class II (special controls). The device is classified as Class II. The special controls for this device are:

(i) Components of the device that come into human contact must be demonstrated to be biocompatible;

(ii) Appropriate analysis/testing must demonstrate that the device is electrically safe and electromagnetically compatible in its intended use environment;

(iii) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. Non-clinical performance testing must characterize the output waveform of the device and demonstrate that the device meets appropriate output performance specifications. The output characteristics and the methods used to determine these characteristics, including the following, must be determined:

(A) Peak output power;

(B) pulse width;

(C) pulse frequency;

- (D) duty cycle;
 - (E) characteristics of other types of modulation that may be used;
 - (F) average measured output powered into the RF antenna/applicator;
 - (G) specific absorption rates in saline gel test load;
 - (H) characterization of the electrical and magnetic fields in saline gel test load for each RF antenna and prescribed RF antenna orientation/position; and
 - (I) characterization of the deposited energy density in saline gel test load.
- (iv) Documented clinical performance testing must demonstrate safe and effective use of the device.
- (v) Labeling must include a detailed summary of the clinical testing pertinent to the use of the device and a summary of the adverse events and complications.

Dated: February 13, 2014.

Leslie Kux,

Assistant Commissioner for Policy.